JOURNAL OF CLINICAL RESEARCH BEST PRACTICES
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Clinical Research Ethics Question of the Month: Ebola Study Enrollment

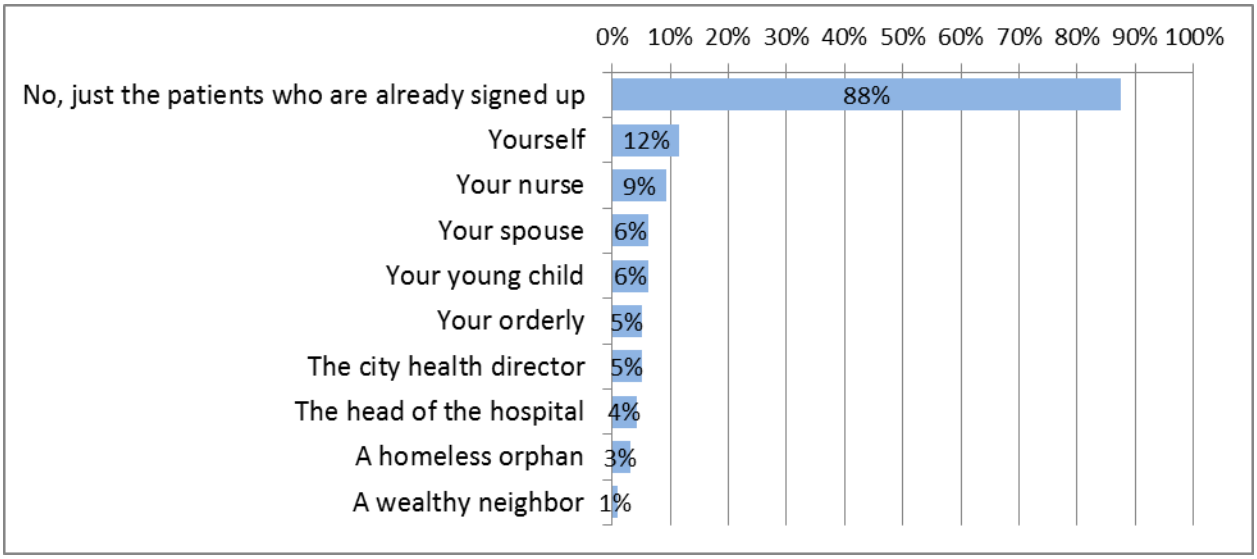
By Norman M. Goldfarb

You are a physician and the principal investigator for a single-site, open-label, fast-acting Ebola vaccine study in West Africa. One hundred doses of the vaccine arrived yesterday. One hundred eligible patients have signed up for the study. The radio this morning reported a major Ebola outbreak in a nearby village. You have no other information to make your decision and no clever way to dodge it. No-one but you will know why any particular person received the vaccine.

Results

The 96 respondents answered the following question:

Instead of the patients that are already signed up for the study, should you enroll any of these people (who are also eligible for the study)?



Respondent Comments

Survey respondents raised some interesting points to consider:

- The news of the outbreak should not impact the people who have already signed up to participate in the study, as it would not be fair to them.
- Vaccinate the PI and also his/her family members, since the disease is contagious, so the study can proceed.
- Vaccinate study staff needed to conduct the study.
- Use the limited resources to ensure that individuals with a significant role in managing the Ebola outbreak are protected first.
- Randomly select at least one local physician who can conduct the study, or you would risk them all dying and stopping the study.

- If any of the 100 people signed up do not attend the vaccination visit, who gets the leftover doses?
- It depends on what the protocol allows.
- If you enroll the new people, you no longer have a study.
- I would not want to introduce bias into the study.
- The vaccine would be labeled for research use only, so you can't use it for the PI, etc.

Discussion

Clinical research professionals indicated a strong preference for protecting the rights and welfare of the study subjects over the health of the medical professionals who would conduct the study and would also be available to provide clinical care to patients who might contract the disease.

Next Month's Question: U.S. Army Interrogation Enhancement Study

You are a member of the U.S. Army's IRB. You are reviewing a study to measure the effects of a drug that appears to enhance the effectiveness of severe methods of interrogation…

Read the rest of the question and give us *your* answer at:
https://www.surveymonkey.com/r/Y6P8F2S

Please send your ethical conundrums to editor@firstclinical.com

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